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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,125	01/12/2004	Dennis R. Burton	48503-00004	3579

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,125	BURTON ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 9, 10, 15-17, 19-22, 28, 29, 34-36, 38-42, 47, 48, 53-55, 57-60, 66, 67, 72-74 and 76, drawn to a mammalian anti-Dengue virus antibody, classified in class 424, subclass 159.1.

II. Claims 4-8, 18 (host cell embodiment), 23-27, 37 (host cell, plant cell embodiment), 43-46, 56, 61-65, 75, 80-84 and 94, drawn to isolated nucleic acid, classified in class 536, subclass 23.53.

III. Claims 11-14, 30-33, 49-52, 68-71 and 87-90, drawn to diagnosing a condition, classified in class 435, subclass 4.

IV. Claims 11-14, 30-33, 49-52, 68-71 and 87-90, drawn to treating a condition, classified in class 435, subclass 4.

V. Claims 18, 37 (transgenic animal embodiment), 56 and 75, drawn to a method for producing anti-Dengue antibody in a transgenic animal, classified in class 800, subclass 4.

VI. Claims 18, 37 (transgenic plant embodiment), 56 and 75, drawn to a method for producing anti-Dengue antibody in a transgenic plant, classified in class 435, subclass 410.

VII. Claims 77-79, 85, 86, 91-93 and 95, drawn to a mammalian anti-Dengue virus antibody that binds an epitope comprising 1-3, classified in class 424, subclass 130.1.

Further restriction is required if Applicant elects an invention that includes SEQ ID NO: 1, 2, 3 or 4, Applicant is required to elect a pair of sequences for search and examination. For example, if Applicant elects SEQ ID NO: 3 (amino acids), then the corresponding SEQ ID NO: 1 (nucleic acids) will also be searched (in the applicable claims that include both the amino aicd and nucleic acid) because SEQ ID NO: 1 encodes SEQ ID NO: 3. The reason for restricting between these sequences is that SEQ ID NO: 3 is an amino acid sequence of a heavy chain of an antibody, while SEQ ID NO: 4 is an amino acid sequence of a light chain of an antibody. These sequences are not identical and therefore require separate sequence searches. The same applies for their respective nucleic acid sequences encoding the amino acid sequences.

2. The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and II are drawn to distinct products: an antibody and a nucleic acid molecule that encodes a variable portion of an antibody. The polynucleotide of group II and the antibody of group I are patentably distinct for the following reasons. The antibody of group I includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group I which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not necessarily encode the antibody of group I because the polynucleotide of group II only has to encode for one variable region, not the exact antibody

contemplated in group I. Therefore the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group II would impose a serious search burden since a search of the polynucleotide of group II would not be used to determine the patentability of an antibody of group I, and vice-versa.

b) Inventions I and (III and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in a method of epitope mapping, which requires different method steps than detecting and treating.

c) Inventions I and (V and VI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody can be made by ligating the various structural components together.

d) Inventions I and VII are distinct antibodies. The antibody of Group VII binds an epitope "comprising 1-3", which is unclear because the "1-3" is not referenced by anything. In the absence of a clear definition of the components of the antibody of Group VII, the antibody of up I and the antibody of Group VII are not the same antibody. The antibodies would be expected to bind different epitopes and have different binding affinities relative to their epitopes.

e) Inventions II and (V and VI) are related as product and process of use. In the instant case, the nucleic acid molecule can be used to detect and characterize anti-DNA antibodies.

f) Inventions II and (III, IV and VI) are unrelated because the methods of Groups III, IV and VII do not require or result in the nucleic acid of Group II.

g) Inventions III and IV are drawn to distinct methods. The method of Group III comprises diagnosing a condition using an anti-Dengue antibody. The method of Group IV comprises treating a condition using an anti-Dengue antibody. Clearly, diagnosing and treating are separate events that require different method steps. The only common reagent in these methods is an anti-Dengue antibody. However, the methods use the antibody to accomplish different goals: detection/diagnosis, and treating to achieve a therapeutic benefit.

h) Inventions (III and IV) and (V-VI) are unrelated because methods of diagnosing and treating a condition are not required to practice the methods of producing antibodies. Methods steps for diagnosing/treating a condition require an antibody, however, the method of producing does not use an antibody, rather, the method results in an antibody.

i) Inventions (III-IV) and VII are unrelated because the antibody of Group VII is not the same antibody that is required to practice the methods of Groups III and IV.

j) Inventions V and VI are distinct methods of producing anti-Dengue antibody. The method of Group V uses a transgenic animal, while the method of Group VI uses a transgenic plant. Methods of using transgenic animals and transgenic plants are classified separately, and require different methods for production of the desired product. For example, producing an antibody in a transgenic plant could be accomplished in a variety of ways, including crossing seeds that contains sequences expressing a light or heavy chain, or introducing sequences for the

light chain into one section of a plant while introducing sequences for the heavy chain into another section of the same plant. These methods cannot be accomplished in a transgenic animal. Therefore, the methods are distinct and separately categorized.

k) Inventions (V and VI) are unrelated to invention VII because the antibody of Group VII is not the desired antibody being produced in the method of Groups V and VI.

Because these inventions are distinct for the reasons given above and the literature search required for one group is not co-extensive for any other group, and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

4. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
March 18, 2005